CHAPTER 5

COST-EFFECTIVENESS OF IMPLANT-SUPPORTED MANDIBULAR REMOVABLE PARTIAL DENTURES

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Abstract

Objectives. Aim of this study was to conduct a cost-effectiveness analysis comparing conventional Removable Partial Denture (RPD) and Implant-supported RPD (ISRPD) treatment in patients with an edentulous maxilla and a bilateral free-ending situation in the mandible.

Materials and methods. Thirty subjects were included. A new RPD was made and implant support was provided 3 months later. Treatment costs (opportunity costs and based on tariffs) were calculated. Treatment effect was expressed by means of the Dutch Oral Health Impact Profile questionnaire (OHIP-NL49), a chewing ability test (Mixing Ability Index, MAI) and a short-form health survey measuring perceived general health (SF-36), which was subsequently converted into Quality-adjusted-life-years (QALYs). The incremental cost-effectiveness ratio (ICER) was the primary outcome measure of cost-effectiveness, comparing both treatment strategies.

Results. The mean total opportunity costs were €981 (95 % CI €971 to €991) for the RPD treatment and €2.480 (95 % CI €2.461 to €2.500) for the ISRPD treatment. The total costs derived from the national tariff structure were €850 for the RPD treatment and €2.610 for the ISRPD treatment. The ICER for OHIP-NL49 and MAI using the opportunity costs was €80 and €786 respectively. When using the tariff structure, corresponding ICERs were €94 and €921. The effect of supporting an RPD with implants when expressed in QALYs was negligible, hence an ICER was not determined.

Conclusions. It is concluded that depending on the choice of outcome measure and monetary threshold, supporting an RPD with implants is cost-effective when payers are willing to pay more than €80 per OHIP point gained. Per MAI point gained an additional €786 has to be invested.

Introduction

Removable partial dentures (RPD's) have a poor reputation as patients frequently complain from a lack of stability and retention, discontinue wearing them or insist on replacement by a new RPD in 25-50 % of cases between 5 and 10 years.[1-3] Supporting an RPD with implants can be beneficial by increasing stability, retention and chewing ability as well as improving patient comfort in general.[4-7] The use of unaesthetic clasps can often be avoided.[8] However, providing implant support to an RPD is likely to increase treatment costs.

In recent years the rise in health care costs has been a controversial topic in the public debate. In the Netherlands for instance, whilst the share of health care costs in the gross domestic product (GDP) in the year 2000 was only 10.4 %, in 2014 it rose to 14.3 %.[9,10] It is uncertain whether health care costs continue to grow at this rate, but it is predicted that the share of health care costs in the GDP will be 22 % in 2040. According to the Dutch Bureau for Economic Policy Analysis (Centraal Plan Bureau, CPB), health care costs rise faster than the country's economic growth.[11] This cannot merely be explained by the fact that the population is aging. Technological advances and increased treatment possibilities are thought to play an important role in the increasing demand for care as well.[12] This increasing demand for care, the associated escalated costs, the limited funds available, and the intent to maintain affordable health care for everyone over the years to come requires an efficient use of available resources.[13]

When competing treatment options are available, their documented or presumed effectiveness and their (additional) costs should be considered and critically assessed when favoring one treatment over the other. A cost-effectiveness analysis can provide insight into whether the more costly treatment option offers sufficient added value to the patient to justify its application. In addition, given similar effectiveness, it could help Health Care Insurance Companies in deciding which therapies to reimburse and which not in order to control expenditures. Currently, in the Dutch setting, economic evaluation is mainly important for new pharmaceuticals, and still has a limited weight in reimbursement decisions. In dentistry in general economic appraisal is not yet widely used either. This can be explained in part by the fact that dental care is usually not paid for by the national health insurance scheme, but mainly through private insurance or out of pocket (for the Dutch situation: circa 73 % in 2011).

Nevertheless, the use of economic evaluation in oral health care is slowly increasing.[14,15] There is a tendency toward a more value-based oral health care system with more emphasis on proven cost-effectiveness and utility of therapies that are provided. In the field of restorative and prosthetic dentistry for example Zitzmann et al. examined the cost-effectiveness of implant-supported overdentures and they found that over an assumed time horizon of 10 years, implant treatment becomes cost-effective

with implant-supported overdentures being the treatment of choice if the patient is willing to pay at least CHF 3800 for a Quality-adjusted Prosthesis Year gained.[16] Single tooth replacement by means of an implant-supported restoration was calculated to be more cost-effective than a 3-unit fixed partial denture.[17-19] In a recent study it was shown that treatment according to the shortened dental arch concept was more cost-effective in improving Oral Health Related Quality of Life (OHRQoL) than replacing missing teeth by means of a removable partial denture.[20] The cost-effectiveness of mandibular overdentures on 2 anterior implants with conventional dentures was compared using the 20-item Oral Health Impact Profile (OHIP-20) instrument as outcome measure. It was concluded that for improvement by one OHIP-20 point CAN$ 14 per year has to be invested (Heydecke et al, 2005). Studies like these can aid dentists and patients to make treatment decisions in the most cost-effective way.[21,22] However, the used outcome measures vary and no study as of yet has operationalized QALY's as an outcome, which is a general measure of health benefits, allowing comparison across different disease areas. No information comparing the anticipated benefits of RPD's and ISRPD's and relating these to the expected extra costs is available.

The aim of the present study is to conduct a cost-effectiveness analysis comparing treatment with RPD and implant-supported removable partial dentures in patients with a bilateral free-ending situation (Kennedy class I) in the mandible and functional complaints.

Materials and methods

Patient population

All data was retrieved from a comprehensive clinical trial on implant-supported removable partial dentures, approved by the Medical Ethical Committee of the University Medical Center Groningen (METc 2011.194) and written informed-consent was obtained from all subjects prior to inclusion. Thirty subjects with a full upper denture and complaints regarding their bilateral free-ending mandibular RPD were included according to the following inclusion criteria:

- minimum age of 18 years;
- bone volume distal from the most posterior abutment teeth allows the placement of implants with a minimum length of 8 mm and minimum diameter of 3.3 mm;
- the patient is capable of understanding and giving informed consent.

Potential subjects with medical and general contraindications for the surgical procedures, those with a history of local radiotherapy to the head and neck region, those who experienced implant loss in the past, subjects who were incapable of performing basal oral hygiene measures and those with decreased masticatory function due to

physical disability or with active, uncontrolled periodontal pathology of the remaining dentition were excluded from participation.

All subject received 4 bilateral implants (Straumann RN, Straumann, Switzerland) provided with cover screws; two implants in the premolar region and two implants in the molar region. After a healing period of 3 months, a new RPD was made. The housing of the Locator® abutment (Zest Anchors, Inc., Escondido, California, USA) was already incorporated in the RPD, but not the Teflon matrix so it neither provided retention nor support to the RPD. Three months later, one single implant on either side (in the premolar (PM) or molar (M) region) was provided with a Locator® abutment. The other implant on either side, was left unloaded for future investigation. Figure 1 shows an example of a typical clinical case.

Patient-based and functional outcome measures were among the parameters of evaluation collected at 3 months of function with an RPD (T_1) and at 3 months of function with implant support (T_2).

Figure 1. Example of a typical clinical case.

Figure 1a. Intra oral situation with 2 implants provided with Locator® abutments in premolar (PM) region. The 2 'sleeping' implants in the molar (M) region are placed for future research.

Figure 1b. Inside of the Implant-supported Removable Partial Denture (showing the matrix which provides support and retention to the ISRPD).

Figure 1c. Kennedy class I ISRPD.

Treatment costs

A cost-effectiveness analysis from a societal perspective was performed to be able to compare treatments that are reimbursed by public insurance. This analysis estimated costs by calculating the opportunity costs of the different procedures. The term opportunity costs refers to the estimation of costs based on the notion that instead of performing the costed activity the relevant professionals could spend their time on another activity (opportunity). Hence the value of these alternative activities represents the opportunity cost of a certain treatment. [23] In practice, this implied assessing the time costs of professionals involved and using the Dutch costing manual and the standard salary scales of the Collective Labor Agreement (CAO) to value this.[24] Because all resource use occurred at the same point in time (2013) discounting was not applicable.

In addition, this cost-effectiveness study was also performed from a payer perspective. This would usually be a private person but could also be a health care insurer. Hence, health care costs were included and valued at their market prices using tariffs for the Dutch situation.

Outcome measures

Three outcome measures were used as effect parameters. The OHIP-NL49 is a validated questionnaire measuring various domains of OHRQoL.[25,26] A chewing ability test (Mixing Ability Index, MAI) was carried out as an objective measure of oral function. Two-colour wax tablets were used to evaluate the ability to mix and kneed a food bolus. After fifteen chewing strokes the mixing of the chewed wax was determined by means of computer analyses of images.[27-29] The MAI has no unit of effect and ranges from 5-30 (respectively fully mixed tablet and pristine tablet). A short-form health survey measured perceived general health (SF-36).[30] The SF-36 dataset was subsequently converted into Quality-Adjusted-Life-Years (QALYs) using the SF-6D excel scoring program provided by the University of Sheffield.[31]

Patients were asked to complete both questionnaires and performed the chewing ability test at 2 moments in time: after having worn a newly made RPD for 3 months (T_1) and 3 months after implant support was provided to the RPD (T_2) (Figure 2).

Figure 2. Timeline. Effect parameters are measured at T1 and T2. RPD: Removable Partial Denture, ISRPD: Implant-supported Removable Partial Denture.

Cost-effectiveness

The incremental cost-effectiveness ratio (ICER) represents the difference in costs divided by the difference in effects between the 2 treatment strategies and is expressed by the following formula:

$$\frac{costs\ A - costs\ B}{effects\ A - effects\ B} = \frac{\Delta C}{\Delta E}$$

Here, costs A are the average costs per patient for ISRPD treatment and costs B are the average costs per patient for RPD treatment. Effects A and B are the average effects per patient for ISRPD and RPD treatment respectively. The ICER was calculated for the 2 treatment strategies, both from a payer perspective and from a societal perspective and was determined for the 3 outcome measures mentioned before. It describes the costs per additional unit of effect for the ISRPD treatment compared to an RPD treatment and as such is a measure of efficiency.[23]

Statistical analysis

To analyze the data Microsoft Office Excel (2011) was used. Uncertainty around the outcome measures was estimated using bootstrapping, generating 5000 replications of the original data set and creating a 95 % confidence interval (CI). Bootstrapping is a simulation based way to estimate the uncertainty around a certain statistic which was based on a random sample. It is performed by generating a large number of new simulated samples by sampling with replacement from the original random sample.[32] To reflect uncertainty around the opportunity costs, a 10 % margin was assumed around the established total time requirements of the professionals. A uniform distribution of actual time was then assumed within this range and used to estimate the variation in costs over individual patients. No uncertainty range was set around the costs based on the tariff structure, because these are fixed values. To visualize the uncertainty in costs and effects a scatter plot of these simulated incremental costs and effects is displayed in the cost-effectiveness plane.

Results

Clinical outcomes

Fifteen men and fifteen women were included with a mean age of 61.0 ± 6.6 years. The mean gain in OHRQoL (OHIP-NL49), after bootstrapping and correcting by multiplying with -1 so that a lower score constitutes a better result, was 18.8. The mean improvement in chewing ability as expressed by the MAI, after bootstrapping and correcting by multiplying with -1 so that a lower score constitutes a better result, was

1.9. A small mean decrease in QALYs was found, i.e. -0.01 (Table 1).

Treatment costs

The mean total opportunity costs were €981 (95 % CI €971 to €991, median €981, range €946-€1028) for the RPD treatment and €2.480 (95 % CI €2.461 to €2.500, median €2.480, range €2.386-€2.559) for the ISRPD treatment. The total costs derived from the national tariff structure were €850 for the RPD treatment and €2.610 for the ISRPD treatment. The breakdown of the costs is presented in table 2.

Cost-effectiveness

The incremental cost ratios for the 2 treatment options and corresponding outcome measures (OHIP-NL49, MAI, QALYs) are presented in Figure 3 and table 3. The ICER for the outcome measure OHIP-NL49 using the opportunity costs was €80. This means that per OHIP point gained an additional €80 has to be invested. The ICER for the outcome measure OHIP-NL49 using the tariff structure based costs was €94, implying that that per OHIP point gained an additional €94 has to be invested. The ICER for the outcome measure MAI using the opportunity costs was €786. Hence, per MAI point gained an additional €786 has to be invested. The ICER for the outcome measure MAI using the tariff structure based costs was €921, implying that per MAI point gained an additional €921 has to be invested. The ISRPD had hardly any effect when expressed in QALYs, which would lead to very high ICER in terms of costs per QALY.

Table 1. Mean effects after bootstrapping for the Oral Health Impact Profile (OHIP-NL49), for the Mixing Ability Index (MAI) and for the Quality Adjusted Life Years (QALY). 95% confidence interval (CI) between brackets. RPD: Removable Partial Denture, ISRPD: Implant-supported Removable Partial Denture, CI: confidence interval.

	OHIP-NL49 95% CI	MAI 95% CI	QALY 95% CI
T1: RPD	41.1 (31.2-52.5)	20.2 (19.4-20.9)	0.8 (0.8-0.8)
T2: ISRPD	22.4 (15.6-30.3)	18.3 (17.8-18.7)	0.8 (0.7-0.8)
Δ T2-T1	18.8* (11.3-28.0)*	1.9* (1.2-2.7)*	-0.0 (-0.0-0.0)

* Corrected by multiplying with -1 so that a lower score constitutes a better result.

Table 2. Mean opportunity costs and costs based on tariff structure for Removable Partial Dentures (RPD) and Implant-supported Removable Partial Dentures (ISRPD). Range because of uncertainty labor costs ± 10 % between brackets.

	RPD	ISRPD
Opportunity costs		
Labor costs dentist*	€455	€663
Labor costs Oral and Maxillofacial Surgeon and assistant (incl. 42 % overhead)*		€242
Invoice laboratory work (excl. VAT)	€530	€1037
Purchase price implants and abutments (excl. VAT)		€530
Total opportunity costs	**€985**	**€2472**
(range labor costs ± 10 %)	(€939-€1031)	(€2381-€2562)
*Costs (tariff)***		
Labor costs dentist	€320	€320
Labor costs Oral and Maxillofacial Surgeon		€720
Invoice laboratory work (excl. VAT)	€530	€1040
Purchase price implants and abutments (excl. VAT)		€530
Total costs (tariff)	**€850**	**€2610**

* Cost manual Hakkaart-van Roijen standard salary scales of Collective Labor Agreement 2013-2015 (CAO UMCs), including Labor costs Oral and Maxillofacial Surgeon and assistant.
** www.nza.nl

Table 3. Incremental costs ratios (ICER) for Removable Partial Dentures (RPD) and Implant-supported Removable Partial Dentures (ISRPD) using the Dutch Oral Health Impact Profile questionnaire (OHIP-NL49), the Mixing Ability Index (MAI) and the Quality Adjusted Life Years (QALY) as outcome measures.

Type of costs	Effect	Incremental costs (€)**	Incremental effects*	ICER**
Opportunity costs	OHIP	€1500	18.8	80
	MAI	€1500	1.9	786
	QALY	€1500	-0.0	N/A
Costs (tariff)	OHIP	€1760	18.8	94
	MAI	€1760	1.9	921
	QALY	€1760	-0.0	N/A

* Displayed numbers are rounded to one decimals, full numbers were used for analysis.
** Displayed numbers are rounded to tens.

Figure 3. Incremental cost-effectiveness analysis based on opportunity costs or health care costs using Dutch tariffs for 3 different outcome measures: Dutch Oral Health Impact Profile questionnaire (OHIP-NL49), Mixing Ability Index (MAI) and (Quality Adjusted Life Years) QALY.

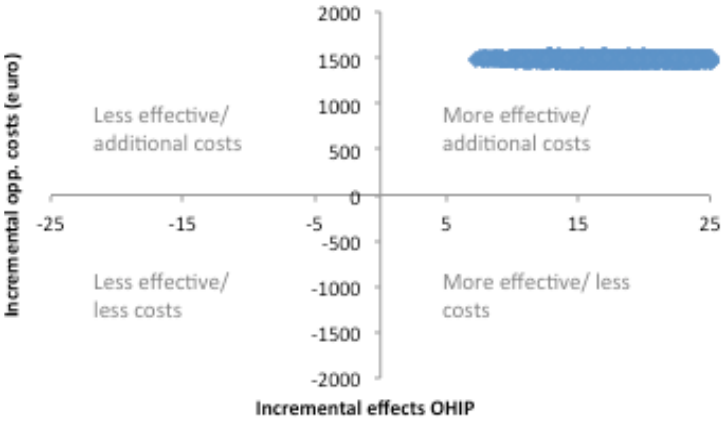

Figure 3a. Analysis based on opportunity costs and OHIP-NL49.

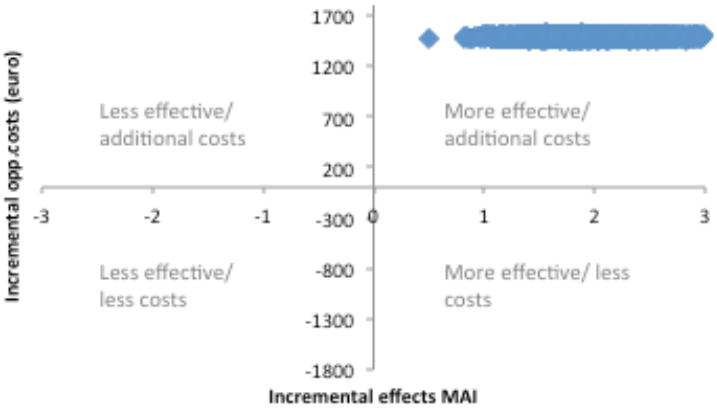

Figure 3b. Analysis based on opportunity costs and MAI.

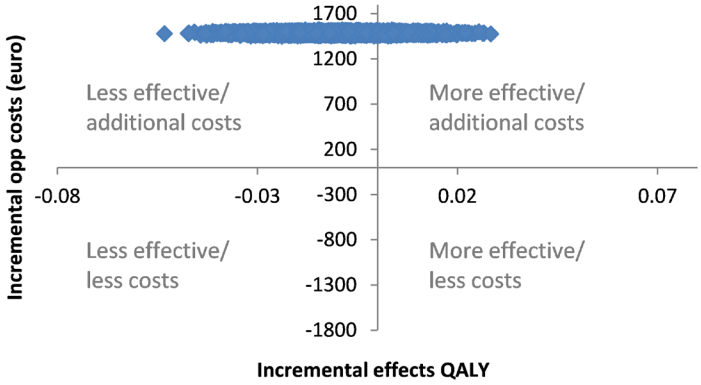

Figure 3c. Analysis based on the opportunity costs and QALY.

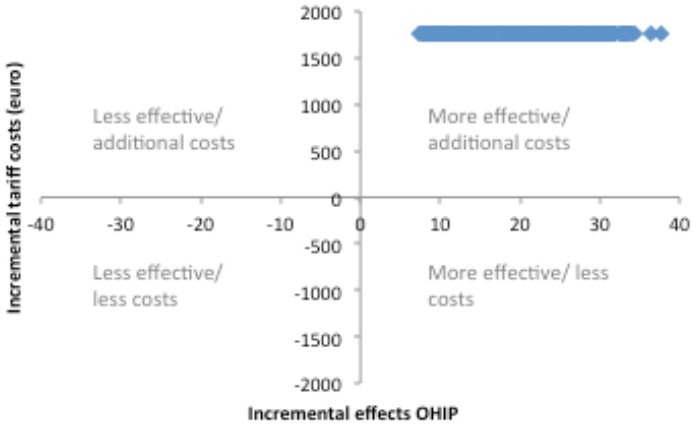

Figure 3d. Analysis based on health care costs using Dutch tariffs and OHIP-NL49.

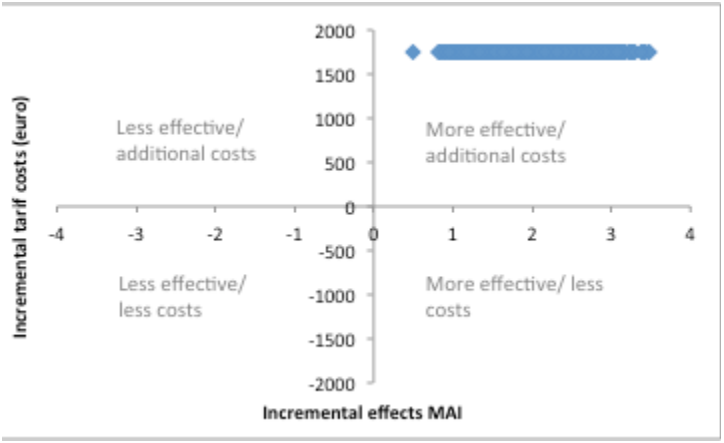

Figure 3e. Analysis based on health care costs using Dutch tariffs and MAI.

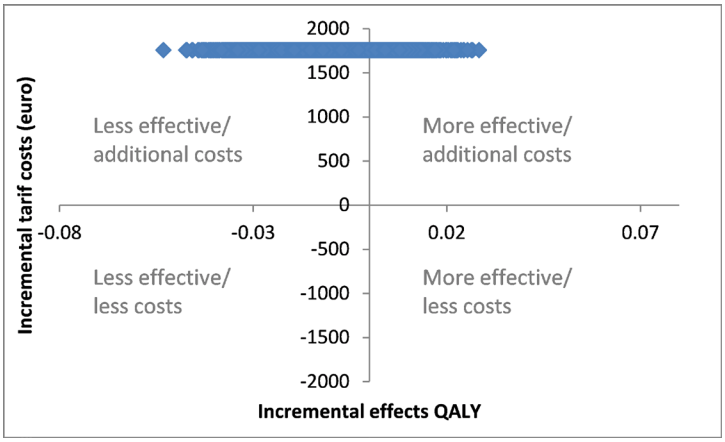

Figure 3f. Analysis based on health care costs using Dutch tariffs and QALY.

Discussion

A cost-effectiveness analysis comparing treatment with a removable partial denture (RPD) and an implant-supported removable partial denture (ISRPD) in patients with a bilateral free-ending situation (Kennedy class I) in the mandible and functional complaints was conducted. The relevance of efforts like the present study are underlined by the conclusions that were drawn in a recent consensus conference on economic evaluation of implant-supported prostheses. They showed that the incremental benefits of implant-supported prostheses came at substantial additional costs. For implant-supported removable partial dentures (ISRPD) a similar result may be expected. It was also stipulated that more economic evaluations are needed that follow well-established methodologies obtained from health economics to better assess the efficiency of implant-supported prostheses.[33] The efforts made in the present paper are in line with this recommendation.

When applying economic evaluation in dentistry, specifically in prosthodontics, several difficulties remain. Attempts at determining the costs of treatment vary widely.[15] The same can be said for outcome measures. A lack of a common outcome measure makes comparison of different treatments complicated.[34] In addition, assessing the value that a patient derives from his dental treatment is difficult and the dental profession has not yet reached consensus on how to measure this added value.[14] Biological, clinical and functional outcome measures are necessary, but equally important are patients' improvements in oral health status, satisfaction, oral and psychological function, self-esteem and quality of life considerations.[34] For economic evaluation in general, an often used outcome is the QALY. This measure can be used over all areas of disease and combines length of life with quality of life. Quality of life is for instance assessed by several validated instruments like the Health Utilities Index 2 and 3 (HUI2, HUI3) and the EuroQol 5D (EQ-5D).[35,36] However, these general instruments are often insensitive to health benefits in dentistry, as we also see in our current study, with negligible changes in SF36 or QALYs based on the SF6 instrument. Attempts have been made to introduce a universal outcome measure similar to the QALY, but specifically for use in dentistry. For example, Zitzmann et al. used Quality-adjusted Prosthesis Years, which is defined as the number of years of service of a prosthesis adjusted by quality, as introduced in the 1990's.[16,37] Unfortunately these attempts are not yet broadly used in literature or validated. In order to overcome this problem, in the present study different outcome measures were used. By using the OHIP-NL49 as a subjective measure for patient perceived oral health quality, the MAI as an objective measure of chewing ability and the QALY as a measure for general health, a wide range of outcomes is covered.

This study shows that when assessing the health benefits using the OHIP-NL49 or MAI, the ISRPD treatment does result in an additional effect, and results ICER's Figure

in the northeast quadrant of the cost-effectiveness plane. In contrast, assessing the cost-effectiveness using QALYs as the outcome measure moves the ICER towards the northwest quadrant of the cost-effectiveness plane, indicating additional cost but no incremental effect. These varying results emphasize the leverage of outcome measure choice when conducting a cost-effectiveness analysis.

Although the number of patients included in this study is relatively small, the minuscule difference in QALY score between the 2 treatment options is noteworthy.[36] SF-36 as an effect measure in prosthodontic treatment is questionable since it has not always proved to be able to discriminate between clinically distinct groups and thus may not be sensitive enough for this purpose.[38] However the SF-36 is a well validated questionnaire and can therefore be assumed to measure what it claims to measure.[30,39] This indicates that no changes to perceived general health can be attributed to supporting an RPD with implants. This underlines the aforementioned importance of outcome measure choice when economic evaluation is used in dentistry. Using more specific measures will help to choose wisely between the various dental procedures.

The finding that 2 procedures made no difference in general health outcomes also raises doubt regarding the manner in which continuous effort is invested in associating dental issues in all fields of study to overall general health matters. A clear improvement in quality of life can be seen after prosthodontic rehabilitation in patients surgically treated for malignancies in the oral cavity resulting in severe comprised oral function and/or esthetics.[40] However, an overestimation of the desired results might occur when less intrusive dental health issues are sought to influence perceived general health and overall quality of life. In addition, the chosen experimental study setup, where patients knew beforehand that after 3 months the already inserted implants were to be used, may have influenced their ratings on the subjective outcome measures to an uncertain degree as a result of cognitive dissonance. Cognitive dissonance can be defined as the discomfort that is experienced by a person who holds contradictory beliefs, in this case that a conventional RPD will not work sufficiently and that implant support will provide the desired additional comfort as projected by the treating physician.[41]

The mean reduction of 18.8 point in OHIP-NL49 is consistent with results found by Gates et al. who reported an OHIP-49 reduction of 11.8 points and several other retrospective studies and case reports using other patient-based measures.[4-7] However, Campos et al (2015) reported median OHIP-49 (Brazilian translation) values of 75 and 10 for RPD's and ISRPD's respectively, hence a far larger improvement for which no explanation can be offered.[42]

A minimal importance difference (MID) of 6 points (95 % CL, 2 to 9) has been suggested for OHIP use in dentistry.[43] The MID was defined as "the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in

the patients' management. As suggested in the same study this MID can be used to approach clinical relevance of changes in perceived oral health. This indicates that the observed reduction of 18.8 OHIP points, leads to a clinically relevant change in oral health related quality of life.

When assessing the clinical relevance of the incremental effects of the MAI there is no such thing as a MID or another threshold available. This makes interpretation of the observed reduction in MAI points difficult. Some insight could be derived from a study on loss of chewing ability after surgery in patients with squamous cell carcinoma of the tongue and/or floor of mouth an average reduction of the MAI score by 2 points was statistically significant (p=0.045).[44] Although this gives a slightly better understanding of the outcome measure it does not provide a threshold to determine whether the results of the current study, with an average increase of 1.9 points, are clinically relevant.

Resource use was determined by interviewing the professionals involved. Timing each individual procedure would have been an even more accurate approach to resource use.

To decide if an intervention is cost-effective and thus offers "good" value for money, the ICER should be compared to a specified monetary threshold as done by Zitzmann et al. [16]. This threshold represents the maximum amount of money that a decision-maker is willing to pay for an additional effect.[45] In the present study the height of the threshold for MAI or OHIP scores was not examined and standardized values are not available, so this could not be determined. An effort to set such a threshold (range) would complement a future study.

Finally, another important factor in assessing cost-effectiveness is the time horizon that is adopted. The current study used a short time horizon, only examining the treatment costs and effects during the timeline of the underlying experimental study. Hence, it only took initial costs and effects of treatment into account. Aftercare costs, other future expenses and the sustainability of the prosthetic solution were not taken into consideration and this would make a valuable addition for further studies. Large, long term benefits of ISRPD that might be expected when supporting an RPD with implants may positively influence its duration and/ or lifetime. This would require sufficient existing evidence concerning long-term outcomes of (IS)RPD's to warrant a modelling approach or a new study to gather such evidence with adequate follow-up time. As in medicine, these longitudinal analyses are complex and difficult to implement.[34] These issues combined with the difficulties referred to above is why further collaboration with health economists to guide future research is advised.[15] An increased proficiency in health care economics amongst dental researchers could favor this collaboration. The data presented in this study could aid patients, health care providers and insurers in decision making from their different perspectives regarding the cost-benefit aspects

of implant retained RPD's. The approach used can serve as an example for addressing other restorative and prosthodontic cost-effectiveness dilemmas.

When SF-36 was used as an outcome measure to determine the impact on general health no incremental effect and thus no added value was found. When outcomes measures were chosen that are dentistry specific, such as MAI or OHIP-NL49, the additional costs of ISRPD's resulted in better outcomes. For the OHIP, the improvement was larger than the MID. For the MAI, although improvement of chewing ability was seen, no MID was available. Consequently, it was not possible to determine whether the observed gain in chewing ability was clinically relevant. Considering the clinical relevance of the gain in OHRQoL, an implant-supported removable partial denture (ISRPD) is cost-effective when payers are willing to pay more than €80 per OHIP point gained. Per MAI point gained an additional €786 would have to be invested.

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